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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,494	11/02/2000	Timothy Samuel Girton	760-35	4895

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EXAMINER

MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 07/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K

<b>Office Action Summary</b>	Application No. 09/704,494	Applicant(s) GIRTON, TIMOTHY SAMUEL	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 January 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION*****Response to Arguments***

Applicant's arguments filed January 14, 2003 have been fully considered but they are not persuasive. Applicant has argued that the Mitchell references teach away from using non-expanded PTFE in the medical field. Examiner disagrees with the applicant. Mitchell does indeed disclose both expanded and non-expanded PTFE materials. Mitchell discloses use of PTFE in the medical field for vascular grafts (col.1, lines 60-61). No where does Mitchell disclose that non-expanded PTFE materials should not be used in the medical field. Because medical grafts are disclosed as one usage for PTFE, one skilled in the art of medical grafts would be inclined to read this patent and be inclined to use both materials non-expanded and expanded for the application of medical grafts. In addition, applicant has pointed to Mitchell column 6, lines 49-60 for possible applications of non-expanded PTFE materials comprising filters, pump packing, insulation for cables and laminates in apparel. Mitchell categorizes filters, pump packing, cable insulation and apparel laminates *with* medical devices (tubes used as replacements for human arteries and veins) on column 1, lines 54-61. It is the examiners position that Mitchell in USPN 4,764,560 and WO 87/02996 does not teach away from non-expanded PTFE usage in the medical field. The medical field is clearly disclosed as one area of application.

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Mitchell (USPN 4,764,560, cited in previous office action). Mitchell discloses a method of producing a porous polytetrafluoroethylene tube useful in medical devices (col.1, lines 60-61) comprising the steps of providing an IPN of siloxane and PTFE (col.6, lines 42-53) and removing said siloxane from IPN (Table 5 shows amount of siloxane extracted), leaving a porous non-expanded PTFE structure (Table 4 shows pore sizes formed).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchell (WO 87/02996, cited by applicant in IDS) in view of Dereume et al. (USPN 5,639,278, cited in previous office action). Referring to claims 1-3, 7-8, 13, and 15-16, Mitchell discloses

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an endoprosthesis for replacing arteries and veins (pg.2, lines 19-20), commonly known in the art as a graft. Mitchell discloses an endoprosthesis that is a non-expanded (pg.19, lines 4-7) porous PTFE material. Mitchell discloses a method of forming the endoprosthesis by providing an IPN of siloxane and PTFE (pg.13, lines 1-11, pg.25, 26, 28) and extracting the siloxane (table 5), leaving a porous polytetrafluoroethylene (table 4). Mitchell does not disclose however using the endoprosthesis to cover a stent surface. Dereume teaches combining a radially expandable stent (22) in between two radially expandable grafts (23, 24), in order to provide increased support, enhanced tissue ingrowth, and means to cover an aneurysm in an artery or vein (col.2, line 64-col.3, line 4; col.3, lines 20-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Dereume's teaching of combining a stent in between two grafts, with Mitchell's type of graft made of non-expanded porous PTFE, in order to provide an endoprosthesis that supports an artery or vein, covers an anerysm, enhances tissue ingrowth, etc. enhancing the overall biocompatibility of the prosthesis.

Referring to claims 4-6, Mitchell discloses a removal of siloxane by chemicals extraction such as toluene (ingredients table 1), or by heat extraction (pg.1, lines 23-25) above a temperature of 300°C (pg.22, lines 1-10).

Referring to claims 9-11, Mitchell discloses a graft endoprosthesis wherein Dereume teaches a graft covered stent, as described above. Dereume further teaches fixing a graft to a stent by methods known in the art, such as silicone or urathane adhesives or heat welding, in order to securely bond the stent to the graft providing a securely attached endoprosthesis. It would have been obvious to combine Mitchell in view of Dereume's stent graft endoprosthesis,

with Dereume's further teaching of bonding means for a graft to a stent, in order to provide an endoprosthesis that is securely attached.

Referring to claim 14, Mitchell discloses a non-expanded porous PTFE endoprosthesis, and an expanded porous PTFE, wherein nodes and fibrils are formed by expanding (pg. 11, lines 23-24), because nodes and fibrils are absent before expansion, it is inherent that nodes and fibrils are absent in the non-expanded porous PTFE.

A note to the applicant: claims 1, 4-6, and 13 are product by process claims. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP 2113.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl L. Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Cheryl Miller

March 25, 2003